HOUSE BILL 1343
By Overbey

SENATE BILL 1112

By McNally

AN ACT to amend Tennessee Code Annotated, Title 56 and Title 63, relative to pharmacy benefits managers.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 6, is amended by adding the following as a new part:

56-6-1001.

The provisions of this part shall be known and may be cited as the "Pharmacy Benefits Management Act." Pharmacy benefits managers shall, and contracts for pharmacy benefits management must, comply with the requirements of this part.

56-6-1002.

(a) As used in this part, unless the context otherwise requires:

(1) "Covered entity" means a health insurance issuer, managed health insurance issuer as defined in § 56-32-228(a), nonprofit hospital, medication service organization, insurer, health coverage plan, health maintenance organization licensed to practice pursuant to title 56, a health program administered by the state or its political subdivisions including the TennCare programs administered pursuant to the waivers approved by the United States department of health and human services, non-profit insurance companies, prepaid plans, self-insured entities, and all other corporations, entities or persons, or an employer, labor union, or other group of persons organized in the state that provides health coverage to covered individuals who are employed or reside in the state. "Covered entity" does not include a health plan that provides

coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, or other long-term care;

(2) "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependant or other person provided health coverage through a policy, contract, or plan for a covered individual;

(3) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration under 21 C.F.R. § 270.20, as amended;

(4) "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, or any of the following services provided with regard to the administration of pharmacy benefits:

(A) Mail order pharmacy;

(B) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(C) Clinical formulary development and management services;

(D) Rebate contracting and administration;

(E) Certain patient compliance, therapeutic intervention, and generic substitution programs; and

(F) Disease management programs.

(5) "Pharmacy benefits manager" means an individual or entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes, but is not limited to, a health insurance issuer, managed health insurance issuer as defined in § 56-32-228(a), nonprofit hospital, medication service organization, insurer, health coverage plan, health maintenance organization licensed to practice pursuant to title 56, a health program administered by the state or its political subdivisions including the TennCare programs administered pursuant to the waivers approved by the United States department of health and human services, non-profit insurance companies, prepaid plans, self-insured entities, and all other corporations, entities or persons acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes, but is not limited to, a mail order pharmacy; and

(6) "Pharmacy" and "Pharmacist" have the same meanings as those terms are defined in § 63-10-204.

56-6-1003.

(a) In performing pharmacy benefit functions, a pharmacy benefits manager owes a fiduciary duty to a covered entity and covered individuals and shall discharge these duties in accordance with the provisions of the Employee Retirement Income Security Act of 1974 ("ERISA"), state and federal law, and this act.

(b) In performing pharmacy benefit functions, a pharmacy benefits manager shall perform its duties with care, skill, prudence, and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of like character and with like aims.

(c) Under a contractual arrangement with a covered entity in performing pharmacy benefit functions, a pharmacy benefits manager shall discharge its duties with respect to the covered entity and covered individuals in careful regard to the interests of the covered individuals and for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses of administering health plans.

56-6-1004.

(a) A pharmacy benefits manager shall notify the covered entity in writing of any activity, policy, or practice of the pharmacy benefits manager that directly or indirectly presents any conflicts of interest with the duties imposed by this act.

(b) A pharmacy benefits manager shall provide to a covered entity all financial and utilization review information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization review information relating to services to that covered entity. A pharmacy benefits manager providing such information or a covered entity may designate this material as confidential. Information so designated may not be disclosed without the consent of the pharmacy benefits manager or covered entity, except where required by law.

(c) A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the state based on volume of sale for prescription drugs or classes or brands of drugs within the state shall for such drugs or classes or brands of drugs prescribed for use in the state pass that payment or benefit on in full to the covered entity or covered individuals.

(d) A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, but not

limited to, formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees that are charged from retail pharmacies and data sales fees.

56-6-1005.

(a) When an audit of records of a pharmacist or pharmacy is conducted by a covered entity, a pharmacy benefits manager, the state or its political subdivisions, or any other entity representing the same, it shall be conducted in the following manner:

(1) Notice shall be given to the pharmacy or pharmacist at least one (1) week prior to conducting the initial on-sight audit for each audit cycle;

(2) Any audit performed under this section which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist licensed by the state under title 63, chapter 10 and practicing pharmacy within the state;

(3) Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record may not, in and of itself, constitute fraud; however, such claims may be subject to recoupment. Notwithstanding any other provision of law to the contrary, no such claim shall be subject to criminal penalties without proof of intent to commit fraud;

(4) A pharmacy or pharmacist may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medical supplies written or transmitted by any means of communication for purposes of validating pharmacy records with respect to orders or refills of a legend or narcotic drug;

(5) A finding of overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of

similar orders or refills for similar drugs; however, recoupment of claims must be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy or pharmacist;

(6) Each pharmacy or pharmacist shall be audited under the standards and parameters as other similarly situated pharmacies or pharmacists audited by a covered entity, a pharmacy benefits manger, the state or its political subdivisions, or any other entity representing the same;

(7) A pharmacy or pharmacist shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) The period covered by an audit may not exceed two (2) years from the date the claim was submitted to or adjudicated by a covered entity, a pharmacy benefits manger, the state or its political subdivisions, or any other entity representing the same;

(9) An audit shall not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled during that time unless otherwise consented to by the pharmacy or pharmacist.

(10) The preliminary audit report must be delivered to the pharmacy or pharmacist within one hundred twenty (120) days after conclusion of the audit. A final audit report shall be delivered to the pharmacy or pharmacist within six (6) months after receipt of the preliminary audit report or final appeal, whichever is later; and

(11) Notwithstanding any other provision of law to the contrary, any audit of a pharmacy or pharmacist shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(b) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeal process as set forth in subsection (c) of this section.

(c) Each covered entity conducting an audit under this section shall establish an appeals process under which a pharmacy or pharmacist may appeal an unfavorable preliminary audit report to a covered entity, a pharmacy benefits manger, the state or its political subdivisions, or any other entity representing the same entity. If, following the appeal, it is determined that an unfavorable audit report or any portion thereof is unsubstantiated, the audit report or such portion shall be dismissed without the necessity of further proceedings.

56-6-1006.

(a) Reimbursement by a pharmacy benefits manager under a contract to a pharmacist or pharmacy for prescription drugs and other products and supplies that is calculated according to a formula that uses a nationally recognized reference in the pricing calculation shall use the most current nationally recognized reference price or amount in the actual or constructive possession of the pharmacy benefits manager or its agent.

(b) For purposes of compliance with this section, pharmacy benefits managers shall be required to update the nationally recognized reference prices or amounts used for calculation of reimbursement for prescription drugs and other products and supplies no less than every three (3) business days.

56-6-1007.

(a) A violation of this act is a violation of §§ 56-8-103 and 56-8-104, as an unfair practice, and shall be punished in accordance with the provisions of title 56, chapter 8, part 1.

(b) In addition a violation of this act is also a violation of the Consumer Protection Act, compiled in title 47, chapter 18.

56-6-1008. The commissioner of commerce and insurance is authorized to promulgate rules and regulations in accordance with the uniform administrative procedures act, title 4, chapter 5 to implement and enforce this act.

56-6-1009. No contract entered into or amended on or after the effective date of this act shall contain provisions in violation of this act.

SECTION 2. If any provision of this act or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

SECTION 3. This act shall take effect July 1, 2007, the public welfare requiring it.